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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,173	12/01/2000	Keisuke Kuida		4567

7590 07/11/2007  
James F. Haley, Jr.  
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1251 Avenue of the Americas  
New York, NY 10020

EXAMINER
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CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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07/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/728,173

Applicant(s)

KUIDA ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 13, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

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Applicant's arguments filed April 13, 2007 have been fully considered but they are not persuasive.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 and 8-11 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a homozygous defect of a Caspase-9 gene, wherein said mouse lacks functional Caspase-9 and exhibits reduced apoptosis in brain, spinal cord, dexamethasone-treated lymphocytes, cardiac muscle, or smooth muscle, or reduced apoptosis associated with viral infection and a method of producing transgenic mouse whose genome comprises a homozygous defect of a Caspase-9 gene, does not reasonably provide enablement for mice where the genetic modification is not integrated into the genome for reasons set forth in the office action mailed October 11, 2006. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a genetically altered mouse deficient in functional caspase-9 expression due to a defective caspase-9 gene, wherein in a homozygous mutation in said defective caspase-9 gene causes reduced apoptosis in brain, spinal cord, dexamethasone-treated thymocytes, cardiac muscle, or smooth muscle, or reduced apoptosis associated with viral infection, and methods of making the genetically altered mouse.

The rejection is directed to the claims encompassing a genetically altered mouse where the defect is not integrated into the genome, but may occur as an extrachromosomal

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DNA molecule. The only enablement is when the defective in the caspase-9 gene occurs within the genome.

Applicant argues the claims do not read on any embodiment where the deficit is not integrated into the genome as the term "homozygous" limits the capsase-9 gene to be an endogenous gene. The artisan, applicant argues, would not believe the term "homozygous" to be associated with extrachromosomal DNA. These arguments are not persuasive.

This is the point made in the office action mailed October 11, 2006. The claims require homozygous and thus are not enabled extrachromosomal. However, extrachromosomal is encompassed by the claims, and is not enabled by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing as they read on a mouse having a defective caspase-9 gene and another genetic alteration. There is no correlation between the genetic alteration and a defective caspase-9 gene.

Applicant argues they are unclear as to "another genetic alteration," but if it is meant to be an "extrachomosomal" DNA, then applicant argues the artisan would not believe the term "homozygous" to be associated with an extrachromosomal DNA moiety.

The rejection is the claim language is confusing because the metes and bounds are not clear. The claims remain unclear; the reader would no know for sure what applicant sees as the claimed invention. The disruption of the caspase-9 gene needs to be clearly linked to the mouse's genome to overcome this rejection.

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The claims are free of the prior art. At the time of filing the prior art did not teach or suggest a genetically altered mouse deficient in functional Caspase-9 expression due to a defective Caspase-9 gene, wherein a homozygous mutation in said defective Caspase-9 gene causes reduced apoptosis in brain, spinal cord, dexamethasone-treated lymphocytes, cardiac muscle, or smooth muscle, or reduced apoptosis associated with viral infection and a method of producing a genetically altered mouse deficient in functional Caspase-9 expression due to a defective Caspase-9 gene.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

July 2, 2007